

May 18, 2018 JCR Pharmaceuticals Co., Ltd.

Translation

JCR Announces Completion of PMDA Review of Clinical Trial Plan for Expanded Indication of GROWJECT® for Short Stature Homeobox-containing Gene (SHOX) Deficiency
-Phase 3 clinical trial to commence in July 2018-

JCR Pharmaceuticals Co., Ltd. (TSE 4552: Chairman and President Shin Ashida, "JCR") announced today that the Pharmaceuticals and Medical Devices Agency (PMDA) completed the review of the clinical trial plan for short stature homeobox-containing gene (SHOX) deficiency as an expanded indication of its core product, GROWJECT<sup>®</sup>, a recombinant human growth hormone product JCR anticipates initiating Phase 3 clinical trial for SHOX deficiency (development code: JR-401X) in July 2018.

SHOX deficiency is a congenital disorder caused by deletions or mutations of a SHOX gene (short stature homeobox containing gene) located on the sex chromosomes which is essential for the skeletal growth. SHOX deficiency will be the fifth potential indication of GROWJECT® which has already been approved for treatment of short stature associated with growth hormone deficiency, turner syndrome, adult growth hormone deficiency, and small for gestational age.

JCR is engaged in a wide spectrum of growth hormone therapy. To improve patient compliance, we launched the liquid formulation of GROWJECT<sup>®</sup> and its dedicated electronically-controlled injector, GROWJECTOR<sup>®</sup> L in January 2017 and have had positive feedbacks from the patients. In addition, Development of a long-acting growth hormone product (development code: JR-142) is ongoing. JCR will continue to strive in providing various treatment options with growth hormone to meet patients' needs.

Our consolidated forecast for this fiscal year ending March 31, 2019 is expected to be minimally impacted.

## [About JCR Pharmaceuticals]

JCR is a specialty pharma engaged in the research, development, manufacture and marketing of biopharmaceuticals and regenerative medicine with a focus on rare diseases. Its philosophy, "Contributing towards people's healthcare through pharmaceutical products" drives JCR to create innovative pharmaceutical products as value-added treatment options for the under-served patient community.

## [Cautionary Statement Regarding Forward-Looking Statements]

This document contains forward-looking statements that are subject to known and unknown risks and uncertainties, many of which are outside our control. Forward-looking statements often contain words such as "believe," "estimate," "anticipate," "intend," "plan," "will," "would," "target" and similar references to future periods. All forward-looking statements regarding our plans, outlook, strategy and future business, financial performance and financial condition are based on judgments derived from the information available to us at this time. Factors or events that could cause our actual results to be materially different from those expressed in our forward-looking statements include, but not limited to, a deterioration of economic conditions, a change in the legal or governmental system, a delay in launching a new product, impact on competitors' pricing and product strategies, a decline in marketing capabilities relating to our products, manufacturing difficulties or delays, an infringement of our intellectual property rights, an adverse court decision in a significant lawsuit and regulatory actions.

This document involves information on pharmaceutical products (including those under development). However, it is not intended for advertising or providing medical advice. Furthermore, it is intended to provide information on our company and businesses and not to solicit investment in securities we issue.

Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the factors that could cause actual results to differ materially, even if new information becomes available in the future.

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